

Application Serial No. 10/675,147
Amendment dated March 1, 2006
Reply to Office Action dated December 1, 2005

REMARKS

Claims 1-27 are pending in the application. Claims 1-27 are rejected. No claims are amended. In view of the discussion below, Applicant respectfully submits that the rejections of the claims have been overcome.

The Invention of the Present Application

The effective administration of medications for the treatment of disease symptoms and for the alleviation of pain, i.e., pain management, is an important aspect to the overall treatment of patients for both curable diseases and terminal illnesses. Oral administration has been widely used for dispensing pain medications such as narcotic and non-narcotic analgesics. However, oral administration is oftentimes not possible due either to obstruction of the oral and gastrointestinal tract or to severe nausea. Further, parenteral administration, including intravenous administration (e.g., I.V. drips), has been used for long-term administration of medication in controlled dosages. However, parenteral administration is invasive and usually painful to the patient. Further, parenteral administration is also not practical for long-term patient care because terminally ill patients may not have the physical capability of performing the injection procedure, and if physically able, may not have the knowledge to properly choose an injection site. Thus, multiple appointments with medical personnel are required.

Thus, rectal administration of medications has become widely used for administering a number of different medications in order to overcome the drawbacks of

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oral and parenteral/intravenous administration. In this method, medications are absorbed through the rectal mucous membranes. However, there are drawbacks with this type of administration, as well, and thus there is need for further improvement for methods of pain management.

These drawbacks have been overcome by the invention of the present application, which includes an infusor system for administering medications to a patient through an indwelling venous needle or venous catheter. This needle or catheter is placed into a superficial vein or veins of the pelvic or inguinal region. A supply of medication is delivered into a tube, and from the tube into the IV needle or indwelling catheter. This system eliminates the large expenses associated with the above-described procedures, which involve administration and continual monitoring by professional medical personnel. The medications dispensed through the infusor system are rapidly and efficiently absorbed into the necessary areas of the body for alleviation of the medical condition or the pain associated therewith.

Further, medications can be delivered into the intraspinal regions through an indwelling needle or catheter. As medication is dispensed, intraabdominal pressure is increased, such as by utilizing an abdominal restraint or binder. The blood flow in the vertebral venous plexus is reversed, and the dispensed medication is delivered from the rectal veins directly into the vertebral bones, the epidural and intrathecal space, and the spinal cord.

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Therefore, the infusor system of the present invention provides a more direct infusion of medication, either continuously or in bolus dosages, into the spinal cord and other vertebral structures as compared to previous oral, parenteral, or rectal administration, for more effective pain management.

Double Patenting Rejections

The Examiner has rejected claims 1-27 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1-22 of U.S. Patent No. 5,846,216 (Gonzales). The Examiner states that although the claims of Gonzales and those of the present application are not identical, they are not patentably distinct from each other because it would be obvious to modify the mucous membrane delivery of Gonzales to venous blood vessel delivery in terms of usage, and use a delivery tube rather than a venous needle in terms of delivery. Applicant respectfully disagrees.

Applicant notes that the Examiner admits in the Office Action that Gonzales shows administration of medications through mucous membranes rather than through a venous blood vessel (i.e., intravenous administration). In the double patenting rejection, the Examiner simply concludes that a modification to delivery via blood vessel, in other words, by intravenous administration, would be obvious in view of Gonzales alone. However, Applicant submits that Gonzales, at least at column 1, lines 34-63, describes various problems with prior parenteral administration (including intravenous administration). Gonzales further describes eliminating the problems found in

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parenteral administration by using an infusor system having a dispenser head operable to direct medication to a mucous membrane to be absorbed and distributed in the body of a patient. Gonzales, in other words, recognizes problems with intravenous administration, and seeks to solve them by delivery via the mucous membranes. This being the case, Applicant submits that there would be no motivation to modify Gonzales to return to using intravenous administration, since Gonzales teaches away from doing just that.

In other words, Gonzales recognizes the myriad of problems with intravenous administration, and resolves those by moving away from intravenous administration to a different form of delivery. By contrast, the present application recognized problems with intravenous administration but finds a way to make such administration work. Since Gonzales explicitly teaches away from intravenous administration, the only way one could reach the invention of the present application in view of Gonzales would be through hindsight with knowledge of the present application. However, such hindsight is improper.

In view of the above discussion, Applicant respectfully submits that the double patenting rejection over Gonzales is in error and requests a withdrawal thereof.

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected each of pending claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over Gonzales in view of one or more other references. First, the Examiner has rejected claims 1 and 27 as being unpatentable over Gonzales

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in view of U.S. Publication No. 2001/0049486 A1 (Evans). The Examiner states that claims 1 and 27 differ from Gonzales in disclosing the administration of medication through venous means (at para. 0036). The Examiner goes on to state that Evans discloses administration of medication through venous means and concludes that it would have been obvious at the time of the invention to one of ordinary skill in the art to administer the medication through a venous blood vessel to improve the function.

Second, claims 5-7 and 22 have been rejected as being unpatentable over Evans in view of Gonzales. The Examiner states that claims 5-7 differ from Evans in disclosing liquid medication, an injection site, and a valve allowing flow. The Examiner states that it would have been obvious to deliver liquid medication through a venous blood vessel in such a manner in order to improve function.

Third, claims 9, 10, 18, and 19 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that these claims differ from Evans in disclosing increased intraabdominal pressure, but that it would have been obvious to use an abdominal binder or restraint in such manner to improve function.

Fourth, claims 16 and 17 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that the claims differ from Evans in disclosing an IV bag with a connecting pump, but that it would have been obvious to use such an IV bag and pump.

Fifth, claims 24-26 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that the claims differ from Evans in disclosing the

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spinal region of the body as the site where liquid medication is delivered, but concludes that it would have been obvious to use the spinal region in such a manner.

Sixth, claims 2, 3, and 8 are rejected as unpatentable over Gonzales in view of U.S. Patent No. 5,061,243 (Winchell). The Examiner states that the claims differ from Evans in disclosing the delivery component with the venous needle, venous blood vessel, and the particular medication. However, the Examiner concludes that it would have been obvious to use the venous needle and medication in such a manner.

And seventh, claims 13-15 are rejected as unpatentable over Gonzales in view of U.S. Publication No. 2002/0188253 A1 (Gordon). The Examiner states that the claims differ from Gonzales in disclosing the method of administering medication, including the initiation of flow of medication at the injection site from a syringe to a tube. The Examiner concludes that it would have been obvious to administer medication in such a manner.

Thus, in rejecting each of claims 1-27 of the application as obvious, the Examiner has used the Gonzales reference in combination with at least one other reference. And, in particular, independent claims 1, 13, and 27 have been rejected as obvious either over Gonzales in view of Evans (claims 1 and 27) or over Gonzales in view of Gordon (claim 13). However, as described above, Gonzales would not be modified to include intravenous administration rather than mucous membrane administration, and thus, the teachings of the other cited references (Evans and Gordon) are immaterial because Gonzales would not be so modified.

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As described above, Applicant notes that the Examiner admits in the Office Action that Gonzales shows administration of medications through mucous membranes rather than through a venous blood vessel (i.e., intravenous administration). Applicant submits that Gonzales, at least at column 1, lines 34-63, describes various problems with prior parenteral administration (including intravenous administration). Gonzales further describes eliminating the problems found in parenteral administration by using an infusor system having a dispenser head operable to direct medication to a mucous membrane to be absorbed and distributed in the body of a patient. Gonzales, in other words, recognized problems with intravenous administration, and resolves those by moving away from intravenous administration to a different form of delivery. By contrast, the present application recognized problems with intravenous administration but finds a way to make such administration work. Since Gonzales explicitly teaches away from intravenous administration, Applicant submits that there would be no motivation to modify Gonzales to return to using intravenous administration.

In view of the above, Applicant submits that the rejection of independent claims 1 and 27 as obvious over Gonzales in view of Evans is in error and should be withdrawn. Applicant further submits that the rejection of independent claim 13 over Gonzales in view of Gordon is in error and should be withdrawn. And thus, Applicant further submits that the rejection of all of their dependent claims is in error and should be withdrawn.

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Conclusion

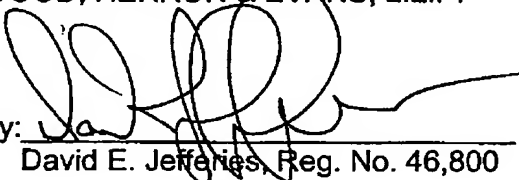
For the foregoing reasons, Applicant submits that all claims are patentable and a Notice of Allowance is respectfully requested.

No fee is believed due. If, however, any fee is deemed due, please charge same to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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